No. 83-1925

IN THE

# Supreme Court of the United States

OCTOBER TERM, 1984

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HILLSBOROUGH COUNTY, FLORIDA, *et al.*,
*Appellants*

v.

AUTOMATED MEDICAL LABORATORIES, INC.,
*Appellees*

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**On Appeal from the United States Court of Appeals for the Eleventh Circuit**

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## APPELLANTS' REPLY BRIEF

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In their opening brief, appellants argued that the Court of Appeals erred in holding that the FDA's regulations, which impose certain minimum standards on plasmapheresis centers, *impliedly* preempted all attempts by Hillsborough County to impose any additional requirements on these centers to protect the public health and safety. Appellee and its *amici* confuse the law of express and implied preemption. If an *express* statement of pre-emptive intent exists, implied pre-emption is not involved; the statement must govern. *Jones v. Rath Packing Co.*,

430 U.S. 519 (1977). Appellee's and its amici's responses to our contentions warrant a brief reply.[1]

### I. The FDA's Clear Statement That It Did Not Intend to Preempt Local Regulation Precludes Implied Preemption.

In 1973, the Commissioner of the FDA stated that the federal plasma regulations "are *not intended* to usurp the powers of state or local authorities to regulate plasmapheresis procedures in their localities." 38 Fed. Reg. 19365 (1973). Incredibly, appellee and ABRA argue that, even though the FDA expressed its intent *not to preempt*, this Court still should imply later preemption by the FDA based upon its subsequent regulations and general statements regarding uniformity.[2] Appellee's suggestion stands the preemption doctrine on its head. Local laws are presumed valid unless federal law clearly requires otherwise. See, *e.g.*, *Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981). Under the theory espoused by appellee and ABRA, whenever a federal agency enacted minimum standards for a particular industry, it would preclude all complementary state and local standards unless it declared expressly

[1] We will refer to the individual *amicus* briefs as follows: the American Blood Commission ("ABC Br."), the American Blood Resources Association ("ABRA Br."), and the Grocery Manufacturers of America ("GMA Br.").

[2] ABRA quotes part of a statement by the FDA as justification for implying preemption of state and local regulation: "The Commissioner finds these (State) programs are inadequate." (ABRA's brief, p. 12, n. 14). The correct quotation is that the Commissioner found state programs "inadequate to keep blood containing hepatitis virus *from the channels of interstate commerce.*" 39 Fed. Reg. 18614-5 (1974). Regulation of interstate commerce is unquestionably an area over which the federal government, as opposed to local government, has primary control. But, conversely, it is local governments' unique power to regulate health and safety procedures in their own localities which led to the FDA's opinion that its regulations do not preempt such powers. 38 Fed. Reg. 19365 (1973); United States' Brief at 18-19.



that it did *not* intend its regulation to be exclusive. Moreover, an agency's declared intention *not* to preempt state law would be effectively nullified each time it adopted new standards. There is no reason for this Court to disregard the FDA's clear statement of its intent not to preempt local regulation.[3]

### II. The National Blood Policy Does Not Require Exclusive Federal Standards.

The goals of the FDA are to ensure, on the one hand, plasma quality and donor safety and, on the other hand, an adequate supply of quality blood. Appellee and ABRA do not claim that the County's regulations would frustrate the goals of donor safety or plasma quality. The basic argument of appellee (Br. 30-31), ABRA (Br. 14-18) and ABC (Br. 18-19) is that the blood supply is a matter of national concern as embodied in the National Blood Policy (39 Fed. Reg. 32702 (1974)).

But, as we pointed out in our opening brief, the National Blood Policy does not include plasmapheresis. As the Acting Assistant Secretary of Health stated: "Although this comprehensive policy accelerates the evolution of an all-voluntary supply of blood and blood components, *it leaves untouched* for the time being, the commercial acquisition of plasma and the preparation and marketing of plasma derivatives, and the commercial acquisition of blood for preparation of diagnostic reagents." 39 Fed. Reg. 32702 (1974) (Emphasis supplied). Although ABRA states (Br. 12 n.13) that commercial plasmapheresis is covered under all aspects of the Policy except its promotion of voluntary donors, the only im-

[3] ABRA argues (Br. 11) that the question of preemption is a legal one and must be decided by this Court, not the federal agency involved. But ABRA's argument disregards the fact that the first *legal* question to be answered by the Court is whether the FDA expressed its intent regarding preemption. As the FDA clearly and expressly did *not* intend to preempt, the legal issue ends there.

pact upon plasmapheresis which the Policy undertook was to "promote the acquisition of information upon which future policy could be developed." 39 Fed. Reg. 32702 (1974).

Based on their view of the National Blood Policy, ABRA and ABC urge that the production of blood products requires a uniform and exclusive set of federal standards.[4] But in fact, most of the arguments of appellee and ABRA are primarily concerned with why they think the FDA *ought* to preempt and not whether it *has* preempted. Whether or not exclusive federal control could be justified as a matter of policy is irrelevant to the issue of whether Congress or the FDA actually intended to preempt all complementary state and local regulation. The arguments concerning the need for absolute uniformity have been presented to the wrong branch of government; it should be Congress or the FDA that determines whether these claims have sufficient merit to take the extraordinary step of ousting all state and local regulation. Since they have not, this Court should not.

Nor is there any basis for inferring any regulatory intent to preempt merely from the existence of minimum standards.[5] ABRA argues that the FDA's standards rep-

[4] Amicus Grocery Manufacturers of America, Inc. is apparently concerned with the economic impact of the local ordinances. This issue arose at trial in the context of appellee's commerce clause challenge, but appellee's speculative evidence, which related most of the increased costs to a 25% decrease in the vendor population, was discounted by the District Court. J.A. 42-43, 46.

[5] Appellee relies heavily upon this Court's decision in *Ray* v. *Atlantic Richfield Co.*, 435 U.S. 151 (1978). But that case is fundamentally different from this one. In *Ray*, the Court held that *Congress* had impliedly and expressly preempted various state efforts to regulate the design or operation of oil tankers operating in navigable waters. Congress' dominant control over navigable waters was the essential basis for the Court's holding that some Washington State laws were preempted. In the Public Health Service Act, Congress has not impliedly preempted any local laws, as the FDA



resent a considered judgment as to the proper balance between the interest of safety on the one hand and the interest of ensuring an adequate supply of blood on the other. From this premise, ABRA asserts that Hillsborough County is precluded from modifying the FDA's judgment as to what standards are appropriate. If ABRA is correct, then all standards set by federal agencies will preempt state law. But the FDA has stated that it sees no threat to a healthy plasma supply posed by the county ordinances.[6] Every federal safety standard embodies a balancing of the amount of protection necessary for public welfare against the expense the regulation will impose on the regulated entity. Additional state and local regulation is valid nevertheless, unless Congress or the regulatory agency makes clear that the balance it has struck is meant to be exclusive and therefore cannot be modified by local law. See *California v. Zook*, 336 U.S. 725, 737 (1949); *Colorado Anti-Discrimination Comm'n v. Continental Air Lines, Inc.*, 372 U.S. 714, 722-724 (1963); L. Tribe, *Constitutional Law* 379 (1978). Because the FDA expressly stated that it did not intend to set absolute standards, this Court need not second-guess that judgment based solely on the FDA's decision to adopt additional minimum requirements.

### III. Federal Regulatory Preemption of Non-conflicting Local Law Requires an Express Statement of Preemptive Intent.

Appellee argues (Br. 16-18) that the County and the *amici* National Association of Counties (NACo), *et*

in effect concluded in its 1973 regulations when it stated that states and localities could continue to regulate plasmapheresis centers.

[6] United States' Brief, pp. 27-28. One possible reason for the FDA's decision not to preempt in a case such as this is the rapidly developing advances in biotechnology, particularly recombinant DNA technology, which may allow the development of substitutes for a variety of plasma derivatives—such as the antihemophiliac factor—before the end of the decade. *See* Office of Technology Assessment, *Summary of Blood Policy and Technology*, Report H-260, at pp. 8, 29-32 (1985).

*al.*, erroneously relied upon *Fidelity Federal Savings & Loan Ass'n v. De La Cuesta*, 458 U.S. 141 (1982), in arguing that regulatory agencies cannot *impliedly* preempt *non-conflicting* state and local regulation. Although the Court need not decide the issue because of the express statement of non-preemptive intent, the Court's prior decisions in *De La Cuesta* and *Capital Cities Cable, Inc. v. Crisp*, —— U.S. ——, 104 S. Ct. 2694 (1984), clearly indicate that an agency's intent to preempt the field must be expressly stated and the exercise of authority must be within the agency's delegated authority.

The cases cited by appellee (Br. 17-18) do not support a contrary rule. They all involved either situations where *Congress* had impliedly preempted the field in its delegations of authority to an agency or instances where the local laws actually have conflicted with the agency's regulations. But here Congress expressed no intent to preempt state or local plasmapheresis regulation and, contrary to the court's assertion, there is no real conflict between the County's ordinances and the FDA's regulations. See Part IV, *infra*. The County simply imposes additional obligations on plasmapheresis centers. Thus, this case clearly presents for the first time the issue of whether federal regulatory agencies can impliedly preempt the field, and, for the reasons stated in our opening brief and more fully set forth in the *amici curiae* brief of NACo, *et al.* (Br. 11-21), the Court should limit federal regulatory preemption of non-conflicting local law to situations where the agency expressly states in its regulation that it intends to exercise exclusive regulatory control.

### IV. The County's Ordinances Do Not Conflict with the FDA's Regulations.

a. Appellee and ABRA attempt (App. Br. 17-18) to retry the case on the issue of whether the County's Ordinances conflict with the purposes or implementation of



the FDA's scheme. They cite appellee's evidence that was introduced in the district court to prove that the Ordinances would increase appellee's cost of doing business. They disregard, however, the district court's express *finding* that this evidence was too speculative to be credited. Thus, there is no factual basis for their claim that the Ordinances will adversely affect the supply of healthy blood.

Moreover, the County has concluded that the additional expense to plasmapheresis centers is necessary to protect the health of the residents of Hillsborough County. The FDA has not denied the County the right to exercise its police powers according to the County's best judgment. If the FDA perceives that local governments are regulating plasma centers too rigorously to the detriment of the nation's blood supply, then the FDA, after notice and comment, can adopt regulations expressly restricting the scope of local regulation. But until it does so, the County's public health interest remains paramount to appellee's and ABRA's interest in pursuing less costly practices that the County believes are potentially unsafe or unhealthy.[7]

b. The remaining claims of conflict are trivial and speculative and, in any event, were not relied upon by appellee in the lower courts. It is clear that none of the Ordinances' additional requirements conflicts with federal law.

First, the registration system will not reduce the amount of plasma a vendor can sell to a particular center; it will merely eliminate the vendor's ability to over-

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[7] In this regard, ABRA's own examples (Br. 24) prove our point. If the FDA can decide to preempt expressly state efforts to regulate tamper-resistant drug packaging and warning labels on drugs for pregnant and nursing women, then it can expressly preempt local laws dealing with the plasma collection process. There is no need for this Court to declare preemption when the regulatory agency has not.

bleed himself by going from one center to another.[8] The cost of the identification card will merely require the individual who profits from selling plasma to share the County's cost of protecting his health and that of the employees of the plasma center. Moreover, if the vendors are truly, as ABRA's brief characterizes (Br. 5) them—"blue collar workers, housewives and university students"—then the County's regulations will not likely deter them from continuing to sell plasma.

Second, the breathalyzer requirement will only screen out people who should not be undergoing the plasmapheresis process anyway. Third, additional local in-

[8] ABRA (Br. 22 n. 36) claims that "[t]here was no evidence presented at trial that the Federal regulations are not adequate to prevent cross-donating." But there was unrebutted testimony of a plasmapheresis expert that the federal government did not develop a reliable registration system (Tr. 183-185), testimony of two FDA representatives that they do not cross check plasma center records in Tampa (Tr. 215, 224), and appellee itself stipulated prior to trial that it never exchanges records with other centers (R. 38, p. 17 ¶ 27).

ABRA argues (Br. 22) that the FDA's requirements that each donor be asked about prior bleeds, that he or she be examined for needle marks, and that protein and hemoglobin levels be tested prior to each bleed are sufficient to safeguard against cross-bleeding. Of course, an inquiry addressed to a person who has a monetary incentive to overbleed himself or herself cannot always be reliable. An examination for needle marks is not always reliable either, since a donor can legally have up to eight needle marks per month under the federal regulations.

Finally, the blood hemoglobin level test is meaningless for the determination of a previous *plasma* extraction, since hemoglobin is a part of the red blood cells which are returned in the plasmapheresis process. ABRA again cites part of an FDA statement to establish that the protein and hematrocrit tests "will indicate whether the donor has subjected himself to overbleeding." The complete sentence says that such tests would indicate whether a donor had subjected himself or herself to the overbleeding of *whole blood* or to plasmapheresis where the *red blood cells* were not returned to the donor. 38 Fed. Reg. 19364 (1973). This case only involves plasma.



spections will only ensure fuller compliance with both local and federal requirements. Certainly appellee cannot claim that the FDA's provision for limited inspections gives plasma centers the right to avoid detection of improprieties at other times.[9]

Both appellee and ABRA assert that the County's additional protections will have no positive health or safety consequences. But that is a judgment the FDA has expressly declared that the County should make and, as the district court found, the County reasonably responded to perceived health concerns in ways that were designed to protect the public welfare. The court of appeals' conclusion that the County's exercise of its police powers is impermissible under the Supremacy Clause of the United States Constitution is unfounded.

## CONCLUSION

For the foregoing reasons and those stated in our opening brief, the judgment of the court of appeals should be reversed.

Respectfully submitted,

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[9] Finally, the pre-screening requirement for hepatitis is simply not an issue in this case. Appellee makes no claim that it has standing to challenge this aspect of the County's Ordinances and therefore the Court should not reach out to decide the issue.